NEWS RELEASE

Moderna Announces Positive Phase 1/2 Data from mRNA-1083, the Company's Combination Vaccine Against Influenza and COVID-19

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mRNA-1083 showed strong immunogenicity against influenza and COVID-19, with an acceptable reactogenicity and safety profile, compared to licensed standalone vaccines

Company to begin Phase 3 trial of mRNA-1083 in adults 50 years and above

CAMBRIDGE, MA / ACCESSWIRE / October 4, 2023 / Moderna, Inc. (NASDAQ:MRNA) today announced positive interim results from the Phase 1/2 trial of mRNA-1083, an investigational combination vaccine against influenza and COVID-19. Moderna's investigational combination vaccines are designed to deliver value to individuals, providers and healthcare systems through higher compliance, easier administration and greater convenience.

"With today's positive results from our combination vaccine against flu and COVID-19, we continue to expand our Phase 3 pipeline," said Stéphane Bancel, Chief Executive Officer of Moderna. "Flu and COVID-19 represent a significant seasonal burden for individuals, providers, healthcare systems and economies. Combination vaccines offer an important opportunity to improve consumer and provider experience, increase compliance with public health recommendations, and deliver value for healthcare systems. We are excited to move combination respiratory vaccines into Phase 3 development and look forward to partnering with public health officials to address the significant seasonal threat posed to people by these viruses."

The ongoing Phase 1/2 clinical trial (ClinicalTrials.gov Identifier: NCT05827926) is a randomized, observer blind study evaluating the safety and immunogenicity of mRNA-1083 compared to a standard dose influenza vaccine,
Fluarix, in adults 50-64 years of age and against an enhanced influenza vaccine, Fluzone HD, in adults 65-79 years of age. For both age groups, mRNA-1083 was compared against Spikevax booster.

The mRNA-1083 candidate selected to advance to Phase 3 achieved hemagglutination inhibition antibody titers similar to or greater than both licensed quadrivalent influenza vaccines and achieved SARS-CoV-2 neutralizing antibody titers similar to the Spikevax bivalent booster in the Phase 1/2 study. mRNA-1083 resulted in geometric mean titer (GMT) ratios $\geq 1.0$ relative to Fluarix in adults 50-64 years of age, for all four influenza vaccine strains. GMT ratios for mRNA-1083 relative to Fluzone HD in adults 65-79 were also $\geq 1.0$, for all four influenza vaccine strains. The GMT ratios of mRNA-1083 relative to Spikevax bivalent were $\geq 0.9$ in adults 50 to 64 years of age and $\geq 1.0$ in adults 65 to 79 years of age, relative to Spikevax.

Reported rates of solicited local and systemic adverse reactions after mRNA-1083 administration were similar to the standalone COVID-19 vaccine group in the trial. The majority of solicited adverse reactions were grade 1 or 2 in severity. Grade 3 solicited local or solicited systemic reactions were reported in less than 4% of participants ages 50 and above. No new safety concerns were identified for mRNA-1083 compared to the standalone vaccines.

The Company plans to begin a Phase 3 trial of mRNA-1083 in 2023 and is targeting potential regulatory approval for the combination vaccine in 2025.

Influenza epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing a substantial burden on healthcare systems. Worldwide, influenza leads to 3-5 million cases of severe diseases and 290,000-650,000 influenza-related respiratory deaths annually, despite the availability of current influenza vaccines. Influenza affects people of all ages, but older adults are disproportionately affected by influenza and its complications. The SARS-CoV-2 virus remains a leading cause of severe illness and mortality throughout the world. Since the start of the pandemic in 2020, there have been approximately 770 million cases of COVID-19 respiratory illness and approximately seven million deaths reported globally. SARS-CoV-2 infects people of all ages, but higher rates of severe illness and death are observed among older individuals and individuals with pre-existing medical conditions.

The global influenza market volume is approximately 500-600 million doses annually with approximately 150 million doses administered in the United States. Moderna estimates the U.S. fall 2023 COVID-19 market size as likely to be 50 to 100 million doses, depending on vaccination rates. Over time, the Company anticipates the COVID-19 market will approach the influenza market in the U.S. given the burden of disease.

The Company previously announced that it expects respiratory product sales in 2027 to be in the range of $8 billion to $15 billion with corresponding respiratory product operating profit in the range of $4 billion to $9 billion.
About Moderna
In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past eight years. To learn more, visit www.modernatx.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: Moderna's development of a combination vaccine candidate against seasonal influenza and COVID-19, mRNA-1083; the potential benefits of combination vaccines; the ability of mRNA-1083 to provide protection against respiratory disease, its safety and tolerability, and protection compared to licensed comparators; the potential timeline for testing and approval of mRNA-1083; the disease burden addressed by respiratory vaccines; and the Company's anticipated future revenues from respiratory product sales and the associated operating profit from those sales. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this press release.

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